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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/686,380

10/15/2003

Theresa Ditter

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EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

01/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/686,380	Applicant(s) DITTER, THERESA	
	Examiner Eric Blatt	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-23-2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 31-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made in the reply filed on March 10, 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Ginn et al. (US 6,896,692) in view of Imran et al. (US 6,535,764).

Ginn discloses a tissue puncture closure device (Figures 3, and 10A-10E) comprising a carrier tube 14, a filament 116, an anchor 120, a sealing plug 12, and a one-way lock wherein said lock comprises a strap and hub ratchet mechanism (Column 19, Lines 24-35). Ginn discloses that the sealing plug 12 is carried over the distal tip of the carrier tube 14 such that the carrier tube 14 may be used to push the plug 12 into position wherein the distal tip of said tube 14 may be slightly compressed thereby releasing the plug 12 (Figures 4A-4D). Since the tissue inherently exerts some proximal force on the plug 12, and the hub and ratchet locking mechanism resists this force, the

locking mechanism applies a pressure to the plug 12 and compresses the plug 12 toward the anchor 120. Ginn does not disclose providing an outer tube/sheath having a diameter greater than that of the plug 12 such that the plug is contained therein for delivery. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide such an outer tube/sheath since the outer surface of the plug 12 is threaded, and providing an outer tube/sheath over said threading would minimize tissue damage during delivery.

Regarding the claimed limitation that the ratchet mechanism is configured to apply a pressure to the sealing plug to form a seal between the tissue wall puncture and the sealing plug wherein the pressure is insufficient to push the sealing plug through a portion of the internal tissue wall puncture, Examiner notes that a method is not claimed and that this language merely requires that the ratchet mechanism is capable of applying a force that is sufficient to form a seal and insufficient to push the plug through a portion of the internal tissue wall puncture. Although Applicant may be correct that the method disclosed in Ginn is not concerned with preventing the sealing plug from being pushed through a portion of the internal tissue wall puncture, this point is not necessarily relevant to the issue of whether the ratchet mechanism is capable of applying a force that will not push the sealing plug through a portion of the internal tissue wall puncture. Ginn discloses that the ratchet elements allow the sealing plug 12 to be advanced in a distal direction but provide a resistive force if the plug 12 is pushed in a proximal direction. Since the ratchet mechanism only maintains the plug 12 in an operator-chosen position and does not independently provide any force to advance the

plug 12, an operator could choose to apply the plug such that it is not pushed through a portion of the internal tissue wall puncture. Thus, the ratchet mechanism it is inherently capable of providing a pressure that is insufficient to push the sealing plug through a portion of the internal tissue wall puncture.

Regarding Ginn's disclosure of the strap and hub ratchet mechanism (Column 19, Lines 24-35), Ginn does not show said mechanism in the figures, but rather, merely states that the puncture closure device may include a locking element comprising a flange that slidably engages ratchet elements disposed on the guide wire element 116. Although it seems clear from this language that the device at least comprises a strap and hub that act as a ratchet mechanism, since this device is not shown in the figures, it is difficult to determine the details of the intended structure. Applicant claims that the strap comprises an elongated track, a plurality of sloping teeth, and a shoulder stop for limiting movement of the hub, and that the hub comprises a nut having a flexible internal finger wherein said finger comprises a notch or an external corner shaped to mate a surface of the plurality of sloping teeth. Examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the apparatus of Ginn with these elements since all of said elements are standard features of a ratchet mechanism and were notoriously old and well known in the art. For further support of the obviousness of said features, Examiner notes Figures 30A-31B of Imran showing a related closure apparatus comprising a ratchet locking mechanism having all of the aforementioned structural elements except for the nut 306 having a flexible internal finger. (The nut 306 is substantially flexible such that it interlocks with the

sloping teeth without necessitating a separate flexible flange) The ratchet mechanism of Ginn, however, already comprises a flexible internal finger. (Column 19, Lines 24-35) It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the apparatus of Ginn with the remaining claimed ratchet elements since Imran teaches that said elements define a functional ratchet mechanism.

Regarding claim 14, Ginn teaches that the interior of the plug comprises material that expands when exposed to fluids such as collagen (Column 10, Lines 42-56). Thus, the plug/external component 12 is a collagen sponge.

Regarding claim 29, as previously discussed, Ginn does not disclose an insertion sheath. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide such an outer tube/sheath since the outer surface of the plug 12 is threaded, and providing an outer tube/sheath over said threading would minimize tissue damage during delivery. Insertion sheaths comprising valves at the ends thereof were notoriously old and well known in the art. It would have been obvious to provide valves at the ends of said sheaths in order to prevent blood or other unwanted fluids from entering the lumen of the insertion sheath.

Response to Arguments

Applicant's arguments filed September 25, 2008 have been fully considered but they are not persuasive. Applicant argues that Ginn fails to teach providing a ratchet mechanism configured to apply a pressure to a sealing plug to form a seal between the tissue wall puncture and the sealing plug wherein the pressure is insufficient to push the

sealing plug through a portion of the internal wall puncture. Applicant may be correct that the method disclosed in Ginn is not concerned with preventing the sealing plug from being pushed through a portion of the internal tissue wall puncture, this point is not necessarily relevant to the issue of whether the ratchet mechanism is capable of applying a force that will not push the sealing plug through a portion of the internal tissue wall puncture. As discussed in the body of the rejection, the ratchet mechanism only maintains the sealing plug in the position that a physician chooses and does not independently provide any force to advance the plug. Since it would be possible for an operator to advance the plug only enough to form a seal between the tissue wall puncture and the sealing plug without pushing the sealing plug through a portion of the internal wall puncture, the ratchet mechanism is capable of providing a force that would maintain the plug in this position.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735.

The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Blatt
571-272-9735

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731